

Application Serial No. 10/675,147
Filed September 30, 2003
Request for Continued Examination dated February 9, 2007
Reply to Office Action dated November 9, 2006
Atty. Docket: SERE-06

REMARKS

Claims 1-27 are pending in the application. Claims 1-27 are rejected.

Claims 1, 13, and 27 are presently amended. In view of the amendments, the Declaration of Gilbert R. Gonzales submitted with the Response dated September 1, 2006, and the discussion below, Applicant respectfully submits that the rejections of the claims have been overcome.

Summary of the Invention of the Present Application

The effective administration of medications for the treatment of disease symptoms and for the alleviation of pain, i.e., pain management, is an important aspect to the overall treatment of patients for both curable diseases and terminal illnesses. Oral administration has been widely used for dispensing pain medications such as narcotic and non-narcotic analgesics. However, oral administration is oftentimes not possible due either to obstruction of the oral and gastrointestinal tract or to severe nausea. Further, parenteral administration, including intravenous administration (e.g., IV drips), has been used for long-term administration of medication in controlled dosages. However, parenteral administration is invasive and usually painful to the patient. Further, parenteral administration is also not practical for long-term patient care because terminally ill patients may not have the physical capability of performing the injection procedure, and if physically able, may not have the knowledge to properly

choose an injection site. Thus, multiple appointments with medical personnel are required.

Thus, rectal administration of medications has become widely used for administering a number of different medications in order to overcome the drawbacks of oral and parenteral/intravenous administration. In this method, medications are absorbed through the rectal mucous membranes. However, there are drawbacks with this type of administration, as well, and thus there is need for further improvement for methods of pain management.

These drawbacks have been overcome by the invention of the present application, which includes an infusor system for administering medications to a patient through an indwelling venous needle or venous catheter. This needle or catheter is placed into a superficial vein or veins of the pelvic or inguinal region. A supply of medication is delivered into a tube, and from the tube into the IV needle or indwelling catheter. This system eliminates the large expenses associated with the above-described procedures, which involve administration and continual monitoring by professional medical personnel. The medications dispensed through the infusor system are rapidly and efficiently absorbed into the necessary areas of the body for alleviation of the medical condition or the pain associated therewith.

Further, medications can be delivered into the intraspinal regions through an indwelling needle or catheter. As medication is dispensed, intraabdominal pressure

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is increased, such as by utilizing an abdominal restraint or binder. The blood flow in the vertebral venous plexus (Batson's Plexus) is reversed, and the dispensed medication is delivered from the rectal veins directly into the vertebral bones, the epidural and intrathecal space, and the spinal cord.

Therefore, the infusor system of the present invention provides a more direct infusion of medication, either continuously or in bolus dosages, into the spinal cord and other vertebral structures as compared to previous oral, parenteral, or rectal administration, for more effective pain management.

Claim Rejections 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 13 and 27 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Examiner states that claims 13 and 27 state the usage of "a venous blood vessel" with respect to positioning of the delivery component, but does not refer back to that venous blood vessel later in the claims. In response, Applicant has amended claims 13 and 27 to refer back to "the" venous blood vessel where appropriate. Applicant therefore submits that the rejection under 35 U.S.C. § 112, second paragraph, has been overcome, and respectfully requests a withdrawal of the rejection.

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Claim Rejections 35 U.S.C. § 103

The Examiner has rejected each of pending claims 1-27 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,846,216 (Gonzales) in view of one or more other references. First, the Examiner has rejected claims 1, 5-7, 9-12, and 16-27 as being unpatentable over Gonzales in view of U.S. Patent No. 6,699,231 (Stermann) or U.S. Patent No. 6,401,719 (Farley). The Examiner states that the claims differ from Gonzales in disclosing the administration of medication through pudic veins. The Examiner goes on to state that both Stermann and Farley disclose administration of medication through pudic veins, and concludes that it would have been obvious at the time of the invention to one of ordinary skill in the art to administer the medication, as in Gonzales, through a pudic vein, as in Stermann or Farley.

Second, claims 2-4 and 8 are rejected as unpatentable over Gonzales in view of Stermann or Farley in further view of U.S. Patent No. 5,061,243 (Winchell). The Examiner states that the claims differ from the combination of Gonzales and Stermann or Farley in disclosing the delivery component with the venous needle, venous blood vessel, and the particular medication. However, the Examiner states that Winchell teaches a venous needle, and concludes that it would have been obvious to use the venous needle and medication with Gonzales (in combination with Stermann or Farley) in such a manner as in the claims.

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Third, claims 13-15 are rejected as unpatentable over Gonzales in view of Sterman or Farley in further view of U.S. Publication No. 2002/0188253 A1 (Gordon). The Examiner states that the claims differ from Gonzales (in combination with Sterman or Farley) in disclosing the method of administering medication, including the initiation of flow of medication at the injection site from a syringe to a tube. The Examiner concludes that such is shown by Gordon, and that it would have been obvious to administer medication in such a manner.

Thus, in rejecting each of claims 1-27 of the application as obvious, the Examiner has used the Gonzales reference in combination with at least one other reference. And, in particular, independent claims 1, 13, and 27 have been rejected as obvious either over Gonzales in view of Sterman or Farley (claims 1 and 27) or over Gonzales in view of Sterman or Farley in further view of Gordon (claim 13).

In response, Applicant first notes that independent claims 1, 13, and 27 as presently amended, recite (1) a delivery component (i.e., the needle or catheter) placed in confronting relationship with a venous blood vessel chosen from a pudic vein, an internal pudic vein, and an external pudic vein, and (2) a pressure-altering device for increasing pressure within the body of the patient to cause reversal of blood flow in Batson's Plexus. Thus, the apparatus of the present application can use the reversal of blood flow in the vertebral venous system (Batson's Plexus) to directly and intravenously administer medication to a patient. As will be described in greater detail

below, such administration would not have been obvious to those of skill in the art in view of the knowledge of rectal administration provided by Gonzales (which represents the state of the art in delivering intraspinal medication by reversal of blood flow in Batson's Plexus prior to the present invention). Further, such administration, by the system of the claimed invention, provides advantages not previously obtained. Thus, Applicant submits that the present claims are not obvious over Gonzales in combination with Sterman or Farley, or over Gonzales in combination with Sterman or Farley in further view of Gordon.

As noted by the Examiner, Gonzales describes a system for rectal administration of medication into a patient body. Medication is dispensed through a delivery tube and to a dispenser head positioned in the rectum of a patient. When delivered rectally, as in Gonzales, medication must be transported across the rectal mucous membranes and then into the patient's vasculature. (See the Declaration of Gilbert R. Gonzales, which was submitted with the Response dated September 1, 2006, another copy of which is attached to this Response). The rectal mucous membranes prevent the passage of large molecular drugs, and thus only a certain limited number of drugs can cross the rectal mucous membranes.

In the present application, a system is disclosed for administering medications by catheterization (or use of a needle or other delivery component) of the pudic vein, the internal pudic vein, or the external pudic vein. Thus, medication can now

be directly administered to a patient's intraspinal area via veins that directly communicate with Batson's Plexus (to the exclusion of cross-communication with any other vascular region). However, until the claimed invention of the present application, drugs were not administered intravenously to be directed to the intraspinal region by increasing intraabdominal pressure to cause reversal of blood flow in Batson's Plexus. (See Declaration of Gilbert R. Gonzales submitted with the Response dated September 1, 2006). And, until the present invention, rectal administration was the only sort of administration of drugs that was successfully used to direct drugs into the bloodstream to thereafter be subjected to reversal of blood flow in Batson's Plexus. Thus, while Applicant acknowledges that needles and catheters are well-known tools of intravenous administration, and rectal dispenser heads are well-known tools of rectal administration, a system including a delivery component in confronting relationship with a pudic vein (in the claimed system) for delivery via reversal of blood flow in Batson's Plexus, was not well known, and would not have been obvious.

For example, there are several advantages that can be obtained from catheterization of one of the family of pudic veins, as in the present invention, as recited in claims 1, 13, and 27 (and as discussed in the Declaration of Gilbert R. Gonzales, submitted with Response dated September 1, 2006). None of these advantages can be obtained via rectal administration. For example, pudic vein catheterization allows for the patient to be upright and ambulatory during the dispensing of medication. This

contrasts with the rectal dispenser head mucous membrane infusion of Gonzales, wherein a patient must remain recumbent during the dispensing of medication. Further, previous drugs that could not be infused rectally (for example, those with structure too large to cross the rectal mucous membranes) can now be administered by pudic vein delivery. Further, massive drug deliveries can be given through catheterization of the pudic vein. The rectal dispenser head mucous membrane infusion method exhibits an across-the-membrane rate limiting effect, which requires relatively potent drugs to be delivered (due to the relatively low volume per time of infusion). However, through a system including IV pudic vein delivery, which is now possible due by the present invention, one can deliver high volumes of low potency drugs. And further, because the pudic veins directly communicate with Batson's Plexus (to the exclusion of any cross-communication with other vessels), medications may be delivered directly to Batson's Plexus without the medication being diluted by diversion to other vessels. In the previous rectal dispenser head mucous membrane infusion of Gonzales, drugs could not be focused to particular veins (such as the pudic veins), and thus would also enter vessels having cross-communication with other vessels of the body. Thus, delivery of medication in rectal dispenser head mucous membrane infusion is more dilute and less effective. Applicant submits that given all these advantages, if pudic vein catheterization, and thus IV delivery of medication via reversal of blood flow in Batson's Plexus were obvious, it certainly would have been done previously. As it was not done,

Applicant submits the claimed system was not obvious over Gonzales in view of Sterman or Farley, or over Gonzales in view of Sterman or Farley in further view of Gordon.

Further, Applicant submits that one skilled in the art would not be motivated to combine either Sterman or Farley with the teaching of Gonzales to reach the invention as claimed. This is because both Sterman and Farley disclose completely different apparatus, methods, and treatments than that disclosed and claimed in the present application. As described above, the invention as claimed delivers medication to a patient by accessing a pudic vein and using the reversal of blood flow in Batson's Plexus. Sterman, however, describes a process that is not contingent upon reversing the flow of blood in a plexus of the body. Rather, Sterman occludes blood flow in order to perfusate an organ. Sterman describes inserting balloon catheters in the arteries and veins of a target organ, and then using the balloon catheters to occlude blood flow to and from the organ while perfusating the organ with a therapeutic agent. Sterman merely lists the pudendal veins as just one example of the various blood vessels one could use in inserting the balloon catheter to cut off blood flow (not reverse blood flow). There is absolutely no similarity between the method of Sterman and the method of the present application, and thus there would be no motivation to combine the two. In fact, occluding blood flow, as taught by Sterman, would be antithetical to the claims of the

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present application, which recite reversal of blood flow (i.e., blood flow still occurs in the claims of the present application, whereas it is halted in Sterman).

Like Sterman, Farley discloses a completely different apparatus, method, and treatment, which is not compatible with that described and claimed in the present application. Farley is directed to a catheter that includes leads having electrodes that are used to heat tissue of an anatomical structure (such as a fallopian tube) to reduce the diameter of that structure in order to ligate or occlude it. Any delivery of medication described by Farley merely occurs to deliver medication to the structure that is being ligated or occluded. Like Sterman, Farley merely recites pudendal veins as an example of veins where the catheter can be inserted. Again, this is incompatible with the claims of the present application, which discuss a reversal of blood flow in a plexus in order to deliver medication. Applicant submits that there is simply no reason why one skilled in the art would look to either Sterman or Farley to combine with the teachings of Gonzales to reach the invention as claimed in the present application.

In view of the above, Applicant submits that the rejection of independent claims 1 and 27 as obvious over Gonzales in view of Sterman or Farley has been overcome and should be withdrawn. Applicant further submits that the rejection of independent claim 13 over Gonzales in view of Sterman or Farley in further view of Gordon has been overcome and should be withdrawn. And thus, Applicant further

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submits that the rejection of all dependent claims has been overcome and should be withdrawn.

Conclusion

For the foregoing reasons, it is submitted that all claims are patentable, and a Notice of Allowance is respectfully requested.

The Commissioner is authorized to charge the Request for Continued Examination fee under 37 C.F.R. 1.17(e) in the amount of \$395.00 to Deposit Account No. 23-3000. It is believed that no other fees are due. If any other fees are deemed due to complete this communication, the Commissioner is authorized to charge same to Deposit Account No. 23-3000. Any other deficiencies or credits necessary to complete this communication should be applied to Deposit Account No. 23-3000.

The Examiner is invited to contact the undersigned attorney with any questions or remaining issues.

Respectfully submitted,
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